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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,663	11/29/2001	Lorraine Faxon Meisner	36091-701.501	5796

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WILSON SONSINI GOODRICH & ROSATI  
650 PAGE MILL ROAD  
PALO ALTO, CA 94304-1050

EXAMINER
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CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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03/30/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/997,663	<b>Applicant(s)</b> MEISNER, LORRAINE FAXON	
	<b>Examiner</b> FRANK I. CHOI	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 25-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/30/2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

Although item nos. 1-8 have been lined through on the PTO-1449 accompanying the IDS filed 6/30/2008, the Examiner did consider the same. Said items were lined through because it would be improper to cite them on the front page a patent as they refer to documents which are not open to the public - office actions and amended claims in applications which are either currently being prosecuted or abandoned and not otherwise open to the public, for example, as a priority application in an application which has been issued as a patent.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 25-27 requires that "at least 10% ascorbic acid be present in a concentrated ascorbic acid solution". There is no support for said limitation Paragraph 00028 of the Specification requires that the concentrated ascorbic acid solution is prepared separately. As such, since water is contained in the composition in addition to the concentrate aqueous ascorbic solution, the ascorbic acid that was provided by the concentrated ascorbic acid solution is no

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longer in the concentrated ascorbic acid solution. Further, claim 26 omits a necessary element in the method steps in that the addition water (not the water that is part of the concentrated ascorbic acid solution) is not included in the method steps of preparing the composition.

Claims 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how “at least 10% of the ascorbic acid is present in a concentrated ascorbic acid solution” when the all of the ascorbic acid is part of a composition which also contains water which not part of the concentrated ascorbic acid solution. Since the water and concentrated ascorbic acid solution are mixed together the ascorbic acid provided the concentrated ascorbic acid solution is no longer part of the same but is dispersed throughout the composition.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,217,914 in view of Bassford et al., Pchelintsev (US Pat. 5,972,993) and EP 0 771 557.

Claim 7 of said US Patent discloses a topical composition comprising at least about 5% (w/v) ascorbic acid, water, having a pH which is adjusted to about 3.6 to about 4.1 wherein at least about 10 wt% of the total ascorbic acid is pretreated ascorbic acid and the pretreated ascorbic acid is produced by dissolving at least about 20% (w/v) ascorbic acid in water at 60 to 90 degrees Celsius, where the composition further contains glucoseamine. The term "pretreated" is defined by the Patent to include cooling below about 40 degrees Celsius after dissolving ascorbic acid in the heated water (US Pat. '914, Column 5, lines 10-36). As such, the same is included within the scope of patent claim.

Pchelintsev discloses that topical application of an antioxidant, such as ascorbic acid, is effective in reducing the redness, flushing and blushing associated with either sensitive skin or rosacea (column 4, lines 35-56). It is disclosed that the amount of antioxidant can range from 0.001 wt% to about 100wt% but that for practical reasons creams, emulsions, lotions or gels would require concentrations of antioxidants that are less than 50 wt% (Column 6, lines 49-68).

EP 0 771 557 discloses the use of ascorbic acid, preferably in the amount of 1 to 20% by weight, for treatment of acne, preferably at a pH of 2 to 5, particularly at a pH of 4 (Page 2, lines 30-58, Page 3, lines 1-7).

The US patent claims the above composition. The difference between the claimed composition and the claims of the present application is that claim 7 of the US Patent does not

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expressly disclose treatment of rosacea or acne. However, the term the prior art amply suggests the same as the prior art discloses that ascorbic acid is effective in the treatment of rosacea (Ptchelintsev) and acne (EP 0 771 557). As such, one of ordinary skill in the art would have expected that the ascorbic acid composition would be effective in topically treating rosacea and acne.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claim 7 of US Pat. 6,217,914 to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of claim of said US Patent and the cited references.

The Examiner has duly considered the Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Claims 25, 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 14, 20 of U.S. Patent No. 6,444,699 in view of Setnikar et al.

Claims 6,14,20 of said US Patent disclose a composition having a pH of 3.6 to 4.2, water, 5 to 25 (w/v)% pretreated ascorbic acid and an aminosugar anti-inflammatory compound. The term "pretreated" is defined by the Specification to mean ascorbic acid which has been dissolved in water at about 60 to about 90 degrees Celsius to form a concentrated solution which contains at least 20% (w/v) ascorbic acid and cooled to below about 40 degrees Celsius (Column 5, lines 10-26).

Setnikar et al. disclose that glucosamine is an aminomonosaccharide having a pharmacological therapeutic index with respect to antiinflammatory activity that is comparable or superior to that on known non-steroidal anti-inflammatories (Abstract).

The US patent discloses the above composition. The difference between the claims of said US Patent and the claims of the present Application is that the claims of said US Patent do not disclose glucosamine as the aminosugar anti-inflammatory compound. However, the prior art amply suggests the same as the prior art disclose that glucosamine is an aminosugar and that it has anti-inflammatory activity. As such, one of ordinary skill in the art would expect that glucosamine would be suitable for use as an aminosugar anti-inflammatory compound.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claim 6, 14, 20 of US Pat. 6,444,699 to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the claims of said US Patent and the cited reference.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The rejection herein is based on an obvious double patenting rejection. This is not a statutory double patenting rejection, as such, there is no requirement that the patent claims claim the same thing as the claims of the present Application only that the application claims be an obvious modification of the patent claims. Since the method claims of the patent disclose a composition, it would be readily apparent to one of ordinary skill in the art that the disclosed composition can be claimed as a composition claim. As such, the mere fact that the patent

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claims are directed to method claims and the present application claims are drawn to a composition does not overcome the rejection herein.

*Conclusion*

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
March 30, 2009

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616